REMARKS

A corrected Inventor's Declaration is submitted herewith.

The Abstract has been corrected to avoid the use of the legal phrases noted by the Examiner. Withdrawal of the rejection thereto is respectfully solicited.

Claim 1 has been amended so that it is directed to the oral heparin composition consisting essentially of the continuous lipid component and the heparin, and a new claim 31 to that composition in the form of a tablet has been presented. The tablet composition claims 2-4, 6, 8, 10-11 and 13-14 have been canceled and re-presented as new claims 32-40. Other then correcting the informalities noted by the Examiner in paragraph 5 of the Office Action and providing the antecedent basis noted in paragraph 8 of the Office Action, the scope of these now canceled claims has not been altered. In light of this change, it is respectfully submitted that the objection and rejection in paragraphs 5 and 8 of the Office Action can be withdrawn.

Claims 1 and 15 has been amended to further specify the polar and non-polar lipids in light of the Examiner's observations in paragraph 7 of the Office Action and it is respectfully submitted that this amendment has rendered the rejection under 35 U.S.C. 112, first paragraph, set forth in that paragraph of the Office Action moot.

Claim 15 has been amended to refer to the formation of the liquid continuous lipid phase and solution of heparin.

The reference to the powdery product in claims 17 and 18 has been deleted and the wording in claim 19 changed to avoid the redundancy noted by the Examiner. In addition, the wording of claim 26 has been changed to make it clear that the tablet consists essentially of the solid oral heparin composition and optionally an inert

nucleus. Claims 29 and 30 have been amended as suggested by the Examiner and claim 29 has further been amended to make it clear that the tablet is administered to a human.

As a result of the foregoing amendment, the claims of this application are directed to a solid oral heparin composition, a tablet containing such composition, a process for making the tablet and the use of the tablet. Since this is a national phase of a PCT application, unity of invention is still present.

The claims which were directed to the tablet were rejected under 35 U.S.C. 102 or 103 over Herslof. These rejections are respectfully traversed.

The tablet claimed in the present application comprises a solid oral heparin composition disposed in the form of a tablet in which the solid oral heparin composition has a melting point of at least 25 degrees C and consists essentially of a continuous lipid component comprising a polar and non-polar lipid, optionally with water and/or an alcohol, and heparin. The Herslof reference does not teach or suggest a solid oral heparin composition in any form.

Herslof relates to spherical lipid bilayers formed in vivo (biosomes) and a matrix thereof (biosome forming matrix or BFM). The BFM is not a solid but instead is a liquid or semi-solid as indicated at column 4, lines 27-28. The fact that the composition is a liquid or semi-solid is also acknowledged in the first line of claim 1. The reference does disclose BFMs containing a low molecular weight heparin sold under the trademark Fragmin but this is a liquid which would either reinforce the liquid nature of the BFM if the BFM was liquid or make the BFM even less solid when it was a semi-solid in the first instance. Since Herslof fails to teach a solid composition having a melting point of at least 25 degrees C, a novelty rejection based on 35 U.S.C.

102 is clearly untenable. Since Herslof does not teach or suggest how a solid material should be made, a rejection based on Section 103 is also inappropriate.

The claims of this application were also rejected under 35 U.S.C. 103 over Nyqvist in view of Rosenberg (using the corresponding U.S. published application as an English language equivalent). This rejection is also respectfully traversed.

The disclosure of Nyqvist is essentially the same as that of Herslof. This is not surprising since the Nyqvist invention is based on the lipid system described in a Swedish patent application (column 1, lines 23-24) which is the priority application on which Herslof is based. Some of the examples in the two patents appear to be the same (compare Nyqvist example 7 with Herslof example 15). It appears that the essential difference between these two references is that one does not contain water and the other does. Accordingly, Nyqvist suffers from the same deficiencies as Herslof in that it discloses a liquid or semi-solid composition rather then a solid composition and tablet containing the solid composition.

The deficiencies in Nyqvist are not remedied by reliance on Rosenberg. This additional reference relates to formulations based on the combination of, inter alia, heparin with a formulation base which contains both a lipid component and a polymer component. It is clear from the disclosure of this reference that absent the polymer, the composition is not a solid. In this connection, the attention of the Examiner is respectfully invited to paragraph [0052] which states:

> "the polymer component of the formulations of the invention can also be understood as a polymeric binder which at least partially forms a polymer matrix. Binders for the purpose of the invention are solid, meltable solvents. The polymer matrix

serves especially to take up, and in particular dissolve, at least a part of the liquid component and this preferably leads to the formation of molecular dispersions."

A molecular dispersion is where a component is "homogeneously dispersed in a solvent". See paragraph [0043]. The examples in Rosenberg further show that not only is the polymer component a material which has a material effect on the characteristics of the composition, but also the amount of the polymer has a material effect. Thus, examples 1 and 2 in Rosenberg disclose preparing solid products from which tablets can be made and in which the polymer constitutes either 64 or 70% of the composition. In contrast, the composition of example 5 which contained 3% of the polymer was a liquid composition which could be packed into hard gelatin capsules while still warm. As will be appreciated by the Examiner, the "consisting essentially of" language in the instant claims serves to exclude the presence of the polymer which effects the basic characteristics of a lipid-heparin combination by sorbing the combination to realize a solid composition.

In light of all of the foregoing considerations, it is respectfully submitted that the prior art does not teach or suggest a solid oral heparin composition nor a tablet containing the solid oral heparin composition nor a method of using the tablet nor a

method of making the tablet. Accordingly, withdrawal of all of the rejections under 35 U.S.C. 102 and 103 is respectfully requested.

Respectfully submitted,

Dated: March 16, 2006

By Edward A. Meilman

Edward A. Meilman
Registration No.: 24,735
DICKSTEIN SHAPIRO MORIN &
OSHINSKY LLP
1177 Avenue of the Americas
41st Floor
New York, New York 10036-2714
(212) 835-1400
Attorney for Applicant